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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,136	07/26/2001	Ricardo Rocha	S03357/1/US	8218

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,136	ROCHA ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-86,91 and 96* is/are pending in the application.

4a) Of the above claim(s) *77-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-76,91,96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2004 has been entered.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 72-76, 91, and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The term "significant" in claim 72 is a relative term which renders the claim indefinite. The term "significant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The claims are indefinite as to the diuretic or anti-hypertensive effect encompassed thereby.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 72-76, 91 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Grob et al. (US 4,559,332).

Grob et al. teaches a method of controlling hyperaldosteronism in human comprising administering a 20-spiroxanes, wherein eplerenone is a preferred compound. The daily effective amount is in the range of 5 mg to 200mg. See, particularly, column 1-3, column 15, lines 44-50, and the claims. Note patient take the medicine as instructed by Grob would have been inherently practice the claimed method, i.e., preventing myocardial infarction. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating or preventing a malady or disease with old and well known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance

the proffered claims from the anticipated therapeutic utility, renders such claims anticipated by the prior inherent use.

3. Claims 72-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Thosar et al. (US 6,410,054).

1. Thosar et al. teaches a composition comprises eplerenone as the active ingredients for treating myocardial infarction. The daily amount of eplerenone is about 0.33 to 2.67 mg/kg body weight. See, particularly, column 3, lines 19-34, column 4, lines 4 to column 5, line 56, and the claims. The amounts disclosed meet the limitation "therapeutical effective amounts" herein claimed. See, pages 38-39 herein as to the effective amount herein required, and pages 97-98 for the diuretic effect of eplerenone. It is noted that Thosar et al. do not teach expressly the diuretic effect. However, It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."

Claim Rejections 35 U.S. C 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 72-76, 91, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grob et al. (US 4,559,332) in view of MacLaughlan et al. (WO 96/24358).

Grob et al. teaches a method of controlling hyperaldosteronism in human comprising administering a 20-spiroxanes, which is an aldosterone antagonist, wherein eplerenone is a preferred compound. The daily effective amount is in the range of 5 mg to 200mg. See, particularly, column 1-3, column 15, lines 44-50, and the claims.

Grob does not teach expressly teaches that the method may be employed for treating myocardial infarction, or in a low amount that would not introduce diuresis.

However, MacLaughlen teaches that aldosterone antagonist is known to be useful for treating circulatory disorders in a low amount that not introduce diuresis, particularly for treating or retarding the development of congestive heart failure. See, particularly, the abstract, pages 7-8 and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Grob's method for treating myocardial infarction in an amount that does not produce diuresis.

A person of ordinary skill in the art would have been motivated to employ Grob's method for treating myocardial infarction because aldosterone antagonist are known to be useful for treating or retarding the development of congestive heart failure, particularly in an low amount that does not produce diuresis. Note, myocardial infarction is an underline etiology of congestive heart failure. Further, the optimization of a result effective parameter, e.g., effective amount, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

6. Claims 72-76 and 91 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thosar et al. (US 6,410,054) in view of McLaughlin et al. (WO 96/24358).

7. Thosar et al. teaches a composition comprises eplerenone as the active ingredients. Thosar further teaches that the composition is useful for the prophylaxis and treatment of various cardiovascular disorders, including myocardial infarction. The daily amount of eplerenone is about 0.33 to 2.67 mg/kg body weight. See, particularly, column 3, lines 19-34, column 4, lines 4 to column 5, line 56, and the claims.

8. Thosar et al. does not teach expressly for treating myocardial infarction wherein the method does not produce diuretic effect.

However, MacLaughlan teaches that aldosterone antagonist is known to be useful for treating circulatory disorders in a low amount that not introduce diuresis, particularly for treating or retarding the development of congestive heart failure. See, particularly, the abstract, pages 7-8 and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the composition disclosed by Thosar et al for prophylaxis or treatment of myocardial infarction wherein the method does not produce diuretic effect because the composition are known to be useful for such purpose, and a therapeutical amount of aldosterone antagonist without produce diuresis is sufficient to provide therapeutical benefit for treating circulatory disorders. Further, the optimization of a result effective parameter, e.g., effective amounts, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Response to the Arguments

Applicants' amendments and remarks submitted June 28, 2004 have been fully considered, but are not persuasive to the rejections set forth above.

The amendment of claim 72, changing "substantial" to "significant," does not cure the indefinite problem. Particularly, the application provides no clear definition as to "significant." Note, absent definition, one of ordinary skill in the art would not be reasonably appraised of the scope of "differ significantly" employed by applicant in the response.

2. Applicants further asserts that because Grob et al. require the combination of second, diuretic compound, and therefore, Grob et al. do not anticipate the claimed invention. The arguments are not persuasive. First, the claims herein do not exclude second therapeutical agents; further, Grob et al. teach that the steroid compounds can be used alone. See, col. 1, lines 48-56. Further, as to an amount "that produces no substantial diuretic or anti-hypertensive effect in the subject," note such amounts disclosed in the specification are 100 mpk (page 98 of the specification). The amounts disclosed by Grob et al. certainly meet this limitation. The instant claims are directed to effecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (erection dysfunction) for the compounds, e.g., eplerenone, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant

invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates.

Applicants contend that the claimed invention is not obvious over the cited prior art because Grob suggest a low dosage is not necessary, wherein a low dosage is required by the claimed invention. The arguments are not persuasive. Note, the range disclosed by Grob, or Thosar, is within, overlapping, or touching the claimed range. It is noted that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990). Further, in view of the teaching by MacLaughlan, one of ordinary skill in the art would be motivated to optimize the amount so that no diuretic effect would produced. Further, if a low dosage of therapeutic agent is known to be effective for treating a disorders, it would have been obvious to one of ordinary skill in the art to employ the low dosage instead of a higher dosage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
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